

## Telasorb® sterile



Spec.-No.: **D 2.5552**  
 Department: CMO-DGM  
 Date: 2016-11-25

### 1. General Product Description

Telasorb® X-ray detectable, white, prewashed disposable laparotomy sponges, with Telatrast® X-ray detectable chip and loop securely sewn into the sponge.

Telasorb® carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class IIa medical device.

A conformity assessment has been performed for Telasorb® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Telasorb®, therefore, is ensured if the product is used in line with the intended purpose.

### 2. Application / Indication

Telasorb® for staunching bleeding and for wound treatment, for gripping or retaining body tissue during laparotomy.

### 3. Presentations

Sterile, 20 threads, 4 packaging levels with lot coded counting card.

	4-ply, white	6-ply, white
	45 x 45 cm	45 x 45 cm
Dimensions*	20 x 30 cm	
	90 x 8 cm	

\*Original size before washing

### 4. Product Characteristics

Material composition:

lap sponge: 100 % absorbent cotton gauze acc. to EN 14079, chlorine free bleached, white  
 pull loop: 100 % cotton, bleached, dyed blue  
 x-ray detectable chip: PVC with min. content of 60 % BaSO<sub>4</sub>

### 5. Product Requirements

Material: fulfils the requirements EN 14079 (after bleaching)  
 Sinking time: < 10 sec.  
 Water absorption capacity: 6 – 8 g water per g gauze

## Telasorb® sterile



Spec.-No.: **D 2.5552**  
 Department: CMO-DGM  
 Date: 2016-11-25

Number of threads\*: warp: 120/10 cm ± 6  
 weft: 80/10 cm ± 5

\*bleached fabric before washing

Area weight\*: ≥ 27 g/m<sup>2</sup>

\*bleached fabric before washing

Tensile strength dry: warp ≥ 60 N/50 mm  
 weft ≥ 35 N/50 mm

Optical brighteners: none

Sterilization: Ehtylene oxide sterilization acc. to EN 11135 with validated process

### 6. Labelling

Lot-No. with 9-digit code:

<b>Lot. - No.</b>	<b>3</b>	<b>999</b>	<b>01</b>	<b>00</b>	<b>1</b>
<b>Explanation</b>	[3 = 2013]	[999 - 000]	Internal Code		
<b>Definition</b>	Year	Serial production order			

Expiry date: ⌚ Year - Month or Year - Month - Day

Example: 2019 - 06      2019 - 06 - 01

Shelf life: 5 years

The product will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.

## Telasorb® sterile



Spec.-No.: **D 2.5552**  
Department: CMO-DGM  
Date: 2016-11-25

### 7. Packaging

Telasorb® sterile laparotomy sponges are tied in bundles and sealed in packs of 2 or 5 pieces. The sterile packaging is in accordance with DIN EN ISO 11607. The sterile packaging is packed in dispensers and in transport cartons. The transport carton sealed with adhesive tapes and packed onto europallet.

Date: 25<sup>th</sup> November 2016

PAUL HARTMANN AG  
Product Development CMO-DGM

i.A.

A handwritten signature in black ink that reads "Peggy Heel".

Peggy Heel